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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/405,678	09/24/1999	FERNAND LABRIE	P/1259-503	9754

2352 7590 11/05/2002

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EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 11/05/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/405,678

Applicant(s)

LABRIE, FERNAND

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,39,42,45,48,51,54,57,60,63,66,69,72,75,78,81,84,87,90,93,96,99 and 102 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 2,39,42,45,48,51,54,57,60,63,66,69,72,75,78,81,84,87,90,93,96,99 and 102.

DETAILED ACTION

The Request for a Continued Examination (RCE) under 37 CFR 1.114 filed on August 19, 2002 based on parent Application No. 09/405678 is acceptable and a RCE has been established. An action on the RCE follows.

Applicants' species election in the parent application is presumed to carry over to the instant CPA since applicants have not indicated a contrary intention.

Receipt of applicants' remarks submitted August 19, 2002 is acknowledged.

Disclosure Objections

1. The disclosure is objected to because of the following informalities: there is no brief descriptions for figures 10-13.

Appropriate correction is required.

Claim Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 2, 39, 42, 45, 48, 51, 54, 57, 60, 63, 66, 69, 72, 75, 78, 81, 84, 87, 90, 93, 96, 99 and 102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-David et al. (CAPLUS Abstract, AN 1967:505730) and Kelly (US Patent 5, 830,887) in view of Wojtacki et al. (CAPLUS Abstract, AN 1994:479820), Sharma et al. (J. Med. Chem. 1990, 33, pages 3222-3229) and Labrie et al. (WO 96/26201, IDS, GGG).

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1. Ben-Davis teaches that dehydropiandrosterone is known to have antihypercholesterolemic effect. See the abstract. Kelly teaches that estrogen receptors modulator, phyto-estrogen, particular therein, are useful for estrogen related disorders including hypercholesterolemia. See, particularly, the abstract, column 2, lines 23-67.
2. The primary references do not teach expressly the employment of the particular compounds herein as the estrogen receptor modulator or employment of a combination of estrogen receptor modulator and a sex steroid precursor.
3. However, Labrie et al. teach that the compound elected herein is a known estrogen receptor modulator and are known to be useful for treating estrogen sensitive disease. See, particularly, the abstract, page 10, the second paragraph, page 19, the whole page and claims 2 and 4. More particularly, the preferred stereochemistry at C2 position is identical with EM 800, see page 19 and example 4 on page 33. Note Labrie does not identify the stereochemistry at C2 position. However, methods of identifying the stereochemistry of an optical active compound are well known in the art, e.g., X-ray crystallography. Sharma et al. teaches that the compound herein has similar binding activity to tamoxifen. See, particularly, scheme 1 on page 3223, especially compound 25, and Figures 3 and 4. Further, temoxifen is known to be beneficial for lowering cholesterol. See the abstract of Wojtacki et al.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the compound (EM 1538) herein for treatment of hypercholesterolemia and further employ a combination of the compound with a known antihypercholesterol agent, such as dehydropiandrosterone.

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A person of ordinary skill in the art would have been motivated to employ the compound (EM 1538) herein for treatment of hypercholesterolemia because estrogen receptor modulators with similar activity are known to be useful for treatment of hypercholesterolemia. Further, the combination of such an estrogen receptor modulator and a sex steroid precursor which is also known to be useful for treatment of hypercholesterolemia is seen to be obvious it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, the claimed invention which is a combination of two known antihypercholesterolemic agents sets forth prima facie obvious subject matter. See In re Kerkhoven, 205 USPQ 1069. Further, the employment of the particular salts herein, is seen to be a selection from amongst equally suitable material and as such obvious. Ex parte Winters 11 USPQ 2nd 1387 (at 1388).

Response to the Arguments

Applicants' remarks submitted August 19, 2002 have been fully considered, but are not persuasive for reasons discussed below.

4. As stated in an early office action, the evidence provided in the declaration as unexpected and synergistic results is not commensurate in scope with the claims. Specifically, the claimed invention is directed to employment of a general combination of EM -1538 and a sex steroid precursor without any limitation about the ratio of the two components. The claimed invention encompassed any combination of the two ingredients, including a combination in such that is without *synergistic* effect.

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5. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., optimal dosage of each pharmaceutical agents employed in the claimed method) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding the establishment of unexpected results, a few notable principles are well settled. It is applicant's burden to explain any proffered data and establish how any results therein should be taken to be unexpected and significant. See MPEP 716.02 (b). The claims must be commensurate in the scope with any evidence of unexpected results. See MPEP 716.02 (d).

Allowable subject Matter

Claim 96 would be allowable if the claimed method including the functional limitation "synergistic". The subject matter is allowable because data in the declaration by Fernand Labrie submitted July 3, 2001 showing the synergistic effect of the combination of DHEA and EM – 1538 (EM-652.HCl).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Examiner

A handwritten signature in black ink, appearing to read 'S. Wang' with a stylized flourish at the end.

Shengjun Wang

November 2, 2002